COUGH AND COLD HBP- chlorpheniramine maleate, dextromethorphan hbr tablet, coated CHAIN DRUG MARKETING ASSOCIATION INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Quality Choice 44-689

Active ingredients (in each tablet)

Chlorpheniramine maleate 4 mg Dextromethorphan HBr 30 mg

Purpose

Antihistamine Cough suppressant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- temporarily relieves runny nose and sneezing due to the common cold

Warnings

Do not use

if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with excessive phlegm (mucus)
- glaucoma
- a breathing problem or persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

persistent cough lasts for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- do not exceed recommended dose
- adults and children 12 years and over: 1 tablet every 6 hours, not more than 4 tablets in 24 hours
- children under 12 years: do not use

Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, D&C red #27 aluminum lake, FD&C yellow #6 aluminum lake, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-426-9391

Principal display panel

QC_® QUALITY CHOICE

NDC 63868-179-01

*Compare to the active ingredients in CORICIDIN® HBP Cough & Cold

Cough & Cold HBP

Chlorpheniramine Maleate | Antihistamine Dextromethorphan HBr | Cough Suppressant

For People with High Blood Pressure Decongestant-Free

Temporarily Relieves:

Cough Runny Nose Sneezing

16 Tablets

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Coricidin® HBP Cough & Cold.

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www.qualitychoice.com Ouestions: 248-449-9300



COUGH AND COLD HBP

chlorpheniramine maleate, dextromethorphan hbr tablet, coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:638		NDC:6386	8-179
Route of Administration	ORAL				
Active Ingredient/Active Moiety					
Ingredient Name					
Ingred	dient Name		Basis of Str	ength	Strength
CHLORPHENIRAMINE MALEATE (UNII:3U6IO1965U)		PHENIRAMINE -	Basis of Str CHLORPHENIRAMIN MALEATE		Strength 4 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0090J9Z) (CHLOR ROMIDE (UNII: 9D2RTI9KYH		CHLORPHENIRAMIN	NE	
CHLORPHENIRAMINE MALEATE (UNII:3U6IO1965U) DEXTROMETHORPHAN HYDROBI	UNII: V1Q0090J9Z) (CHLOR ROMIDE (UNII: 9D2RTI9KYH		CHLORPHENIRAMIN MALEATE DEXTROMETHORPI	NE	4 mg

Strength

Ingredient Name

CROSCARMELLOSE SODIUM (UNII: M280L1HH48)

D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

STEARIC ACID (UNII: 4ELV7Z65AP)

TALC (UNII: 7SEV7J4R1U)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)

POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)

Product Characteristics			
Color	red	Score	no score
Shape	ROUND	Size	9mm
Flavor		Imprint Code	44;689
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-179- 01	2 in 1 CARTON	03/31/2017	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63868-179- 16	3 in 1 CARTON	03/31/2017	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/31/2017	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	pack(63868-179)	

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(63868-179)